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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,865	07/31/2001	Gideon Strassmann	116-039	2422
47888	7590	06/06/2005	EXAMINER	
HEDMAN & COSTIGAN P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036			LUKTON, DAVID	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/918,865

Applicant(s)

STRASSMANN ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/18/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-21 is/are allowed.
- 6) ☒ Claim(s) 6,7 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Pursuant to the directives of the response filed 3/18/05, claim 18 has been amended, claims 1-5, 8-10, 13-17 cancelled. Claims 6, 7, 18-21 are now pending.

Applicants' arguments filed 3/18/05 have been considered and found persuasive in part.

The rejection of claims 6, 7, and 18-19 under 35 U.S.C. §112 second paragraph is withdrawn.



The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 6, 7, 18 are rejected under 35 U.S.C. §103 as being unpatentable over Sredni (USP 5,475,030).

As indicated previously, Sredni discloses (col 5, line 51+) various tellurium compounds that are asserted to be useful for treatment of cancer, immune deficiencies, autoimmune

diseases and infectious diseases. Sredni does not disclose that animals which are afflicted with one or more of the foregoing diseases can experience weight loss. However, it is known to veterinarians of ordinary skill that animals (including birds) which are stricken with cancer, immune deficiencies, autoimmune diseases or infectious diseases will often suffer a weight loss. Thus, it would have been obvious to one of ordinary skill at the time of the invention that if one of the tellurium compounds of Sredni is administered to an underweight bird that is stricken with cancer, an immune deficiency, an autoimmune disease or an infectious disease, the bird will gain weight if the compounds are effective to eradicate the bird's illness as asserted in the '030 patent.

In response to the foregoing, applicants have argued that "there is no reason to interpret the [claims] as being directed to poultry that are [unhealthy]. The plain meaning of the word 'poultry' is that [it] is directed to a class of animals commonly raised for food production and not to a subclass of unhealthy [birds]". However, at no point has the examiner suggested that the claims are directed solely to a method of treating birds that are afflicted with a disease. In fact, there is no explicit recitation of unhealthy birds in the claims. What the examiner has argued, and reaffirms herein, is that the claims encompass a method of enhancing weight gain in birds that are unhealthy. Applicants have provided no reason as to why the skilled artisan would come to believe that the term "poultry" requires that the birds in question must be free of even the slightest infection. Applicants have provided no reason as to why the skilled artisan would come to believe that if one chicken in a group of

poultry develops an infection, that one chicken ceases to be classified as poultry. As a zoological matter, applicants assertions are not correct, and as a legal matter, applicants assertions are also not correct. That is, what matters in imposing a §103 rejection against a genus is whether there exists at least one embodiment within that genus which is rendered obvious. Such is the case here. Applicants' arguments that the claims exclude unhealthy birds is found unpersuasive for another reason, i.e., the specification itself. At various passages in the specification, reference is made to unhealthy birds. Consider, e.g., the following passages: page 5, line 1; page 5, line 2; page 3, line 32; page 4, line 2, page 4, lines 10-11, and page 4, lines 26-34. It may be that the word "unhealthy" is not explicitly used in these passages. But it is evident that this term is implied. For example, on page 3, line 32, it is asserted that the compounds can "improve the health" of birds. On page 5, line 1, it is asserted that the compounds can be administered to birds that exhibit "failure to thrive". On page 4, reference is made to death and mortality of birds. Thus, it is clear that the claims encompass treatment of birds that are unhealthy.

Applicants have also argued that they have provided "unexpected results". As indicated previously by the examiner, the claims encompass the following four categories of invention:

- (a) juvenile birds in a rapid growth phase, wherein the birds are healthy;
- (b) juvenile birds in a rapid growth phase, wherein the birds are unhealthy;
- (c) fully grown adult birds that are healthy;
- (d) fully grown adult birds that are unhealthy.

If one stipulates that the data on page 15 qualify as “unexpected”, the data would serve to render novel only the first of the four categories of invention. This ground of rejection primarily targets categories (b), (c) and (d), for which there are no “unexpected results”. Applicants have declined to explain why it is that the “unexpected results” overcome the obviousness rejection as it is applied against the other three subgenera.

The rejection is maintained.

[One option might be to limit the claims to enhancement of weight gain in hatchlings (page 4, lines 7-8) or to enhancement of weight gain in chicks].



Claims 6, 7, 18 are rejected under 35 U.S.C. §103 as being unpatentable over Sredni (USP 5,126,149) or Albeck (USP 4,761,490) in view of Lowenthal (USP 6,642,032).

Sredni and Albeck both teach that tellurium compounds are effective to promote production of lymphokines. Such lymphokines include (col 1, line 42, Albeck) *gamma* interferon. Neither of Sredni or Albeck disclose that an effect of increasing production of *gamma* interferon is to promote weight gain in birds. Lowenthal discloses that *gamma* interferon promotes weight gain in birds. Thus, it would have been obvious to one of ordinary skill that administering an organotellurium compound to a bird will result in weight gain.

Applicants’ data on page 15 (specification) is noted. Consider also that the claims

encompass the following four categories of invention:

- (e) juvenile birds in a rapid growth phase, wherein the birds are healthy;
- (f) juvenile birds in a rapid growth phase, wherein the birds are unhealthy;
- (g) fully grown adult birds that are healthy;
- (h) fully grown adult birds that are unhealthy.

If one stipulates that the data on page 15 qualify as “unexpected”, the data would serve to render novel only the first of the four categories of invention. This ground of rejection primarily targets categories (b), (c) and (d), for which there are no “unexpected results”.

In response to the foregoing, applicants have argued that Lowenthal taken by itself would not provide the basis for a valid rejection under 35 USC 102. This particular point is conceded by the examiner.

Applicants have also argued that the four categories of invention referred to above by the examiner are not disclosed in any of the references. This point is also conceded. However, it is entirely appropriate to consider what the claims in question encompass, irrespective of whether the prior art references form a valid rejection of all embodiments in the claims, or only one. Applicants have also argued that the question of whether unexpected results have been obtained is moot, since the examiner has failed to make a *prima facie* case. However, as indicated above, Sredni and Albeck both teach that tellurium compounds are effective to promote production of gamma interferon; Lowenthal discloses that *gamma* interferon promotes weight

gain in birds. Thus, it would have been obvious to one of ordinary skill that administering an organotellurium compound to a bird will result in weight gain. The Lowenthal reference does not require any modification of the procedure which is taught by the primary references; the Lowenthal reference provides an expectation of an outcome resulting from practicing the invention of Sredni and Albeck. Accordingly, the *prima facie* case is on firm ground.

The rejection is maintained.



Claims 6, 7, 18 are rejected under 35 U.S.C. §103 as being unpatentable over Sredni (USP 4,929,739)

Sredni discloses that complexes of tellurium and selenium are effective to treat cancer and immunodeficiency. Sredni does not disclose that animals afflicted with cancer or immunodeficiency often suffer weight loss. However, this is known to the veterinarian of ordinary skill. Moreover, such weight loss is going to be inevitable for animals that must hunt for food. Thus, the veterinarian of ordinary skill would have expected that by administering the disclosed complexes of tellurium and selenium to an underweight animal (e.g., a bird) that is afflicted with cancer or immunodeficiency, the health of the animal will be restored, and normal weight realized.

Applicants have argued only that a rejection under 35 U.S.C. §103 must be based only on terms that are explicitly recited, and not on embodiments that are encompassed by the language of the claims.

However, applicants are not correct; the rejection is maintained.



Claims 6, 7, 18 are rejected under 35 U.S.C. §103 as being unpatentable over Sredni (USP 4,929,739) in view of Lowenthal (USP 6,642,032).

Sredni discloses that complexes of selenium and tellurium are effective to promote production of lymphokines. Such lymphokines would include *gamma* interferon. Sredni does not disclose that an effect of increasing production of lymphokines is to promote weight gain in birds. Lowenthal discloses that a lymphokine (*gamma* interferon) promotes weight gain in birds. Thus, it would have been obvious to one of ordinary skill that administering an organotellurium or organoselenium compound to a bird will result in weight gain.

Applicants have argued that neither reference taken alone forms the basis for a valid §103 rejection, or a valid §102 rejection. Even if this is true, the point is moot. The artisan of ordinary skill would have taken from the Sredni reference that complexes of selenium and tellurium are effective to promote production of lymphokines, and from Lowenthal the fact that lymphokines promote weight gain in birds.

The rejection is maintained.



THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.


DAVID LUKTON
PATENT EXAMINER
GROUP 1800